We are committed to—

Providing Effective, Proactive Leadership on Vaccines and Immunization

The National Immunization Program provides effective, proactive leadership in the immunization arena by fostering sound vaccine recommendations and policies, conducting quality research, developing educational material and enlisting and engaging the contributions of a wide range of professional and other organizations.

Assuring Vaccine Safety

As a leader in immunization safety research and surveillance, CDC plays a vital role in assuring vaccine safety. Sound immunization policies and recommendations affecting the health of our nation depend upon the continuous monitoring of vaccines and ongoing assessment of immunization benefits and risks. Through a multi-faceted approach, CDC's vaccine safety system identifies potential vaccine side effects, conducts epidemiological studies to determine whether a particular adverse event is associated with a specific vaccine,helps determine the appropriate public health response to vaccine safety concerns, evaluates public and health care provider perceptions of vaccination, and communicates the benefits and risks of vaccines to the public, media, and health communities.

Major Events of the Past Year— in Vaccine Safety

Implementation of the Clinical Immunization Safety Assessment Network

Clinically significant adverse reactions following vaccination are rarely seen in clinical trials and health care providers see them too infrequently to be able to provide standardized treatment. The Clinical Immunization Safety Assessment Network (CISA) was, therefore, newly funded in 2001 to assess people who believe they have suffered a severe adverse reaction following vaccination. The results of these evaluations will be used to gain a better understanding of how such events might occur and to develop protocols or guidelines for health care providers that will help them treat other patients in similar situations. In addition, the CISA centers will serve as regional information sources to which clinical vaccine safety questions can be referred.

The primary goals of this network include

- Developing protocols for the clinical evaluation and management of vaccine adverse events
- Improving the understanding of adverse events at the individual level (including determining genetic and other risk factors that may predispose individuals to reactions)
- Serving as a public and health care provider regional referral center for clinical vaccine safety inquiries (such as taking referrals from pediatricians or family practitioners)

Institutes of Medicine Immunization Safety Reviews

In the fall of 2000, CDC and the National Institutes of Health (NIH) requested that the National Academy of Sciences' Institutes of Medicine (IOM) convene an Immunization Safety Review Committee. This independent expert committee is charged with examining three hypotheses about existing and emerging immunization safety concerns each year, through 2003.

During 2001, the committee reviewed

- The hypothesized link between the Measles-Mumps-Rubella (MMR) vaccine and autism
- The hypothesis that thimerosal-containing vaccines may contribute to neurodevelopmental disorders such as autism, learning disabilities, and speech delays
- The concern that multiple immunizations may be associated with immune system dysfunction such as overload of the immune system

Measles-Mumps-Rubella Vaccine and Autism Safety Review

The Concern. In recent years, attention has been focused on a hypothesis that autistic behaviors in children seemed to occur, or to worsen, shortly after receipt of the MMR vaccine. No conclusive data indicate that any vaccine increases the risk of developing autism or any other learning disability. Nonetheless, given the level of concern among parents and others regarding vaccines and autism, the CDC is committed to investigating this issue using the best scientific methods available.

IOM Review and Conclusions. In 2001, the IOM Safety Review Committee assessed the scientific plausibility of the hypothesis that MMR vaccine contributes to the onset of autism spectrum disorders (ASD). In April 2001, the committee concluded that the recent increasing trends in autism diagnoses cannot be attributed to the MMR vaccine. Recognizing that scientific studies can never be absolute in their conclusions, the IOM recommended further research to explore the possibility that exposure to MMR vaccine could be a risk factor for ASD in very rare cases. The committee also concluded that the existing recommendations for routine use of MMR at 12 to 15 months of age and 4 to 6 years of age remain unchanged. The committee recommended that research be intensified in other areas to find the cause and optimal treatment for autism.

Thimerosal and Vaccines Safety Review

Background. Thimerosal is a derivative of ethylmercury and has been used as an additive to vaccines and other products since the 1930s because it is effective in killing bacteria and in preventing bacterial contamination. Even though no harmful effects have been reported from the amounts of thimerosal used in vaccines, in July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure. This was done because any potential risk from mercury is of concern, and the elimination of exposure to mercury in the form of thimerosal from vaccines is feasible, therefore thimerosal should be removed from vaccines as soon as possible. However, there remains no convincing evidence of harm caused by low levels of thimerosal in vaccines.

IOM Review and Conclusions. At the request of CDC and NIH, the IOM Safety Review Committee examined the hypothesis of whether vaccines containing thimerosal could have caused specific neurodevelopmental disorders, including autism, attention deficit/hyperactivity disorder, and speech or language delay. The committee concluded that the existing evidence was inadequate to accept or reject a causal relationship; however, because mercury at high doses can be harmful, the committee noted that the hypothesis was biologically plausible.

The committee also noted that, in cases where only vaccines containing the preservative thimerosal are available, it is better to use them rather than forego immunization. The committee stated that "While the health effects of thimerosal are uncertain, we know for sure that these vaccines protect against real, proven threats to unvaccinated infants, children, and pregnant women."

Current Status of Thimerosal in Vaccines. Rapid progress has been made in reducing thimerosal exposure from vaccines. By the end of 2001, all routinely recommended licensed pediatric vaccines being manufactured for the U.S. market contained no thimerosal or only trace amounts of thimerosal.

Multiple Immunizations and Immune Dysfunction Safety Review

The Concern. Over the past two decades, the childhood immunization schedule has grown in length. In 1980, infants received immunizations against four diseases: diphtheria, tetanus, pertussis, and polio. Today, the routinely recommended childhood immunizations provide protection against 11 diseases—which means that children will not need to receive up to 20 doses of seven vaccines by 2 years of age. According to a recent survey, about 25 percent of parents believed that getting too many immunizations could weaken or "overload" a child's immune system. There are no data to support this hypothesis, but CDC and NIH requested this review to learn more about whether vaccines could adversely affect the developing immune system.

Background. Vaccines consist of antigens (proteins and polysaccharides) and these antigens are needed to produce an immune response. Current data indicate that the number of antigens in the vaccines that make up the recommended childhood immunization schedule has actually decreased over the past 20 to 30 years, despite the increase in the number of vaccines and vaccine doses. This is due to the removal of smallpox and whole cell pertussis vaccines from the childhood immunization schedule.

IOM Review and Conclusions. At the request of CDC and NIH, the IOM Safety Review Committee examined the hypothesis of whether the recommended childhood immunization schedule could overload an infant's immune system. The committee focused on exposure to multiple immunizations in the first two years of life. The committee concluded that multiple immunizations do not increase a child's risk for other kinds of infections or for type 1 diabetes. The committee also concluded that there is not enough scientific evidence to accept or reject the hypothesis of an increased risk for allergic disease, particularly asthma. The committee also learned that scientists estimate that the capacity of the infant immune system is at least 1000 times greater than what is required to respond to immunization. No changes in the current immunization schedule were recommended by the committee.

Significant Achievements— in Vaccine Safety

Vaccine Safety Monitoring and Research Programs and Initiatives

The Vaccine Adverse Event Reporting System

The Vaccine Adverse Event Reporting System (VAERS) is a program for vaccine safety monitoring coordinated by the CDC and the Food and Drug Administration. The Vaccine Adverse Event Reporting System collects and analyzes reports of possible side effects and reactions that occur after the administration of U.S. licensed vaccines. Under the National Childhood Vaccine Injury Act, health care providers and vaccine manufacturers are required to report certain adverse events following vaccination; however, anyone can report a suspected adverse event to VAERS. Vaccine recipients, or their parents or guardians are encouraged to seek help from their health care professional in filling out the VAERS form.

Each year about 10,000 to 13,000 VAERS reports are filed directly by health care professionals, parents, patients, and through vaccine manufacturers. All reports are accepted and entered without determining whether the adverse event could have been caused by the vaccine in question. Approximately 89 percent of the reports describe mild and expected events such as fever, local reactions, episodes of crying or mild irritability, and other less serious experiences. Reports of more serious adverse events are investigated, and those investigations often find that many of the reported adverse events are not caused by vaccines.

Recent enhancements to the VAERS system include the availability of a free public-use dataset and the ability to report adverse events through the Internet. Both are accessible through the VAERS web site at www.vaers.org These improvements will make reporting easier and faster, as well as improve public access to VAERS information.

The Vaccine Safety Datalink

The Vaccine Safety Datalink (VSD) is a database containing comprehensive medical and immunization histories of over 7.5 million people. This project is a collaborative effort between CDC and several health maintenance organizations. The database makes it possible to conduct research studies that compare the prevalence of health problems between unvaccinated and vaccinated people. This improves the ability to determine whether adverse events following immunization are causal or coincidental. The VSD has recently grown from 4 to 8 managed care organizations, is more geographically diverse, incorporates multiple health systems models, and currently includes more than 2.5 percent of the U.S. population.

The Brighton Collaboration

The Brighton Collaboration is an international voluntary collaboration formed to develop globally accepted and implemented standard case definitions for adverse events following immunization. These will be known as the Brighton Standardized Case Definitions. The project began in 2000 with the formation of a steering committee and the creation of the first six working groups. The working groups are comprised of international volunteers with expertise in vaccine safety and in collaboration with regulatory, public health, scientific, professional, and vaccine manufacturing agencies. The guidelines for interpreting, recording, and presenting safety data developed by the collaboration will facilitate the sharing and comparison of vaccine data among vaccine safety professionals.

The Vaccine Identification Standards Initiative

The Vaccine Identification Standards Initiative is a joint, voluntary, cooperative effort between NIP and various partners in the vaccine and immunization system. The group's objective is to establish uniform guidelines and resources for vaccine packaging, labeling, and recording. By doing this, they will enhance the safety of vaccination and the accuracy and convenience of transferring vaccine identifying information into medical records and immunization registries.

Vaccine Safety Research Studies in 2001

The National Immunization Program conducts ongoing vaccine safety monitoring and research to determine if particular adverse events are associated with vaccines. Numerous studies were conducted and published in 2001.

Population-Based Study of Rotavirus Vaccination and Intussusception

***New England Journal of Medicine*, 2002 Jan 17;346(3):211-2.**
***Pediatric Infectious Disease Journal*, 2001;20:410-16.**

During the first year that the rhesus rotavirus tetravalent vaccine (RRV-TV) was licensed, VAERS received 15 reports of intussucception (that is, the infolding of one segment of the intestine within another) after vaccination. To evaluate the risk of intussusception, a study in ten managed care organizations was conducted. The study found that RRV-TV was associated with an increased risk of intussusception. The greatest risk was 3 to 7 days after the first vaccination dose, and the attributable risk was one case of intussusception per 11,073 children vaccinated. The results of this study contributed significantly to the Advisory Committee on Immunization Practice's (ACIP's) decision to withdraw their recommendation for the routine use of RRV-TV in infants, as well as the removal of the vaccine from the market by the manufacturer.

Measles-Mumps-Rubella and Other Measles-Containing Vaccines and Risk for Inflammatory Bowel Disease

***Archives of Pediatric and Adolescent Medicine*, 2001:155:354-359.**

A small study involving 12 children suggested the possibility of an association between the measles vaccine and chronic inflammatory bowel disease. A much larger study was conducted using the VSD to determine if receipt or timing of a measles-containing vaccine increases the risk for inflammatory bowel disease. The VSD study found that the risk of inflammatory bowel disease was not increased by vaccination with MMR or other measles-containing vaccines, nor was the timing of vaccination early in life associated with inflammatory bowel disease.

The Risk of Seizures after Receipt of Whole-cell Pertussis or Measles-Mumps-Rubella Vaccines

***New England Journal of Medicine*, 2001:345:656-61.**

The administration of whole-cell pertussis in the diphtheria-tetanus-pertussis (DTP) vaccine and the MMR vaccine has been associated with rare cases of fever-related seizures. A study published in 2001 found that children who suffered rare fever-related seizures after getting DTP and MMR vaccinations did not have an increased risk for subsequent seizures or neurodevelopmental (such as learning) disabilities. The study confirmed what was already known—that DTP and MMR vaccinations can temporarily increase the risk for fever-related, or what are called "febrile" seizures, in some children. This study also found that no long-term effects could be attributed to febrile seizures following vaccination. Since the period covered by this study, the use of acellular pertussis (DTaP) vaccine has replaced DTP vaccine in the United States. The DTaP vaccine has been associated with fewer side effects than DTP, including febrile seizures.

Childhood Vaccinations, Vaccination Timing, and Risk of Type 1 Diabetes

***Pediatrics*, 2001:108.**

It has been suggested by one researcher that vaccination may contribute to the risk of developing type 1 diabetes, and that the timing of giving certain vaccines to children may influence this risk. This researcher suggests, for instance, that hepatitis B vaccine given at birth decreases the risk of type 1 diabetes; whereas, a first dose given at two months, or later, increases the risk. Other researchers who have studied the possible link between vaccines and diabetes have not found such an association. These other studies, however, did not take into consideration vaccination timing (that is, when a vaccine was given), nor did they include many newer, currently recommended, childhood vaccines. Thus, scientists at NIP used the VSD to study childhood vaccinations, vaccination timing, and risk of type 1 diabetes. This was

the first epidemiologic study to examine the possibility that timing of vaccination might be related to risk of clinical diabetes in children. The results of this study showed that, regardless of the timing of vaccination, type 1 diabetes was not associated with any of the routinely recommended childhood vaccines (including new vaccines such as varicella vaccine).

Inactivated Poliovirus Vaccine Followed by Oral Poliovirus Vaccine

***Pediatrics*, 2001:107:e83.**

A study was conducted to determine if there were an unusual number of adverse reactions reported when a vaccination schedule was used that began with the inactivated poliovirus (IPV) vaccine, but was followed by the oral poliovirus vaccine. The number of adverse reactions were not unusual, which affirmed the safety of IPV and supports the ACIP's recommendation for an all-IPV schedule which is now in use in the U.S.

Economic Value to Parents of Reducing the Pain and Emotional Distress of Childhood Vaccine Injections

***Pediatric Infectious Disease Journal*, 2001:20:S57-62.**

Parents are known to delay individual vaccinations because of the pain and emotional distress resulting from an increasing number of injections. A study was therefore conducted to assess the economic value to parents of combining multiple vaccines in a single shot whenever possible. This would reduce the number of injections a child would receive, but would still give the full recommended protection. The investigators found that parents are willing to pay considerable amounts of money to reduce or avoid the pain and anxiety associated with multiple childhood vaccine injections.

Anthrax Vaccine Safety

The CDC and Department of Defense (DoD) are conducting studies and coordinating activities to improve the effectiveness, safety, and acceptability of the current anthrax vaccine. The National Immunization Program's Anthrax Vaccine Safety Activity (AVSA) is specifically responsible for studying anthrax vaccine safety as well as examining the knowledge, attitudes, and behaviors of military personnel regarding anthrax vaccination. The NIP was involved in the following anthrax vaccine safety activities in 2001.

The Walter Reed National Vaccine Health Care Center

The Walter Reed National Vaccine Health Care Center opened in September 2001. This is the first vaccine health care center (VHC) in the country and the first in what is expected to be a network of centers coordinated by CDC and DoD. The centers will conduct followup and case management of certain military personnel who have experienced adverse events following anthrax vaccination. The knowledge gained from the VHCs will be used to improve the safety and quality of future vaccinations and to increase the confidence of military personnel in the safety of vaccines required by the DoD. In addition, the VHCs should help improve reporting of vaccine-associated adverse events and facilitate further research on adverse events possibly related to vaccination.

Anthrax Vaccine Safety Research

In collaboration with CDC's National Center for Infectious Diseases (NCID), AVSA developed the protocol for a clinical trial to determine if the anthrax vaccine is safe and effective when administered through a different route and in fewer doses. The protocol for the study has been approved, and participant enrollment began in early 2002.

Bioterrorism Response

In collaboration with NCID, AVSA developed protocols for the administration of anthrax vaccine to civilians who were exposed to, or potentially exposed to, anthrax spores following the bioterrorist attacks in Washington D.C., New Jersey, New York, Connecticut, and Florida.

Anthrax Vaccine Communication Activities

The National Immunization Program conducted the following activities to further enhance communication with the public and health care providers about anthrax vaccination.

- Development of a protocol to conduct a national survey of the knowledge, attitudes and beliefs (KABs) among military personnel

and military health care providers regarding the anthrax vaccine and a survey of military and civilian vaccine health care providers KABs regarding reporting to VAERS

- Development of web-based enhanced reporting of anthrax vaccine associated adverse events to VAERS
- Initial development of standardized case definitions for anthrax vaccine associated adverse events (Brighton Collaboration)

Vaccine Risk Communication Activities

Research

The National Immunization Program's Vaccine Risk Communication and Research team regularly conducts research to better understand health professional and public vaccine safety KABs. The group also develops materials that effectively communicate information about vaccine risks and benefits. In 2001, NIP collaborated with the Gallup Organization for an annual survey of physicians and pediatricians to help identify parents' and health care providers' vaccine safety knowledge and concerns. The first survey should be conducted in 2002. In addition, three other vaccine benefit-risk communication studies were conducted in 2001, with expected results in 2002.

- Study of different ways to convey benefit-risk communication in the Vaccine Information Statements (VIS) and other parent-education materials
- Data collected on public perceptions of vaccine safety using Porter-Novelli's American Healthstyles survey
- Study of perceptions of rare risks conduced in collaboration with the Georgia Institute of Technology and the University of Alberta, Canada

Printed Materials

New materials, including brochures, fact sheets, question and answer documents, and resource kits on a variety of topics, are regularly produced to keep health care providers, parents, and the public abreast of the most current information on vaccine benefits and risks.

Website

The National Immunization Program frequently updates its website (www.cdc.gov/nip) to ensure that accurate and timely information can be easily found on vaccine benefits, risks, and safety.

SUCCESS STORY

Vaccine Safety

A Comprehensive Vaccine Safety System

The Clinical Immunization Safety Assessment (CISA) Network is a new initiative to improve scientific understanding of vaccine safety issues at the individual, "patient" level. This is the first network system in the U.S. to investigate and manage vaccine suspected and diagnosed side effects on an individual level. The CISA network will provide parents, patients, and health care providers with an organized system and network to find answers to questions about adverse reactions following vaccination and treatments for reactions, should any occur.

National Immunization Information Hotline

Parents, patients, and health care professionals often call the National Immunization Information Hotline when they have questions or want the most current information on vaccine safety. The toll-free calls can be answered in both English and Spanish, and Tele-Typewriter and American Sign Language services are available to accommodate the hearing impaired. In 2001, the hotline staff responded to over 111,000 calls about immunization issues.

Future and Continuing Activities— in Vaccine Safety

- Increase our knowledge of genetic risk factors for vaccine reactions.
- Utilize information in immunization registries to enhance vaccine safety efforts.
- Increase opportunities for research studies on vaccine risks by qualified external organizations and researchers.
- Improve vaccine benefit-risk communication, including parent and health care professional education, through expanded research and partnerships.

Policies and Recommendations

2001 Recommendations from the Advisory Committee on Immunization Practices

A panel of multi-disciplinary experts who provide immunization advice and guidance to the federal government

Influenza Immunization

In response to the anticipated delay of much of the nations' influenza vaccine for the 2001-02 season, the ACIP issued supplemental recommendations to maximize the protection of people at highest risk of complications from influenza. The optimal time period for influenza vaccination was extended by two weeks, now covering October 1st through November 30th. It was also recommended that health care providers give the first available doses of the influenza vaccine to those at highest risk of complications, and delay vaccinating other patients until November and beyond.

Pneumococcal Conjugate Vaccine

In 2000, the pneumococcal conjugate vaccine was added to the childhood schedule to help protect children from invasive pneumococcal diseases such as pneumococcal pneumonia, meningitis, and bacteremia. Demand in 2001 for the vaccine was greater than expected. Therefore, to ensure that those at greatest need get the available doses, updated recommendations were issued on how best to use available doses.

Vaccinia (Smallpox) Vaccine

In June 2001, the ACIP published recommendations for the use of vaccinia vaccine. These recommendations were made because of the concerns that smallpox may be used as a biological weapon and to revise those recommendations for vaccination of people working with or exposed to the vaccinia virus, recombinant vaccinia virus or other orthopoxviruses that can infect humans.

In the June 2001 recommendations, the ACIP stated that because "the risk for smallpox occurring as a result of a deliberate release is considered low, and the population at risk for such an exposure cannot be determined", the risks of vaccine complications outweigh the benefits for pre-attack vaccination. The ACIP did not recommend pre-attack vaccination for any group other than laboratory or medical personnel working with non-highly attenuated orthopoxviruses. However, the ACIP indicated that if the potential for a smallpox release increased, pre-attack vaccination might be indicated for selected groups who would have an identified higher risk for exposure because of work-related contact with smallpox patients or infectious materials. The ACIP also made recommendations for vaccination following an intentional release of smallpox and the vaccination of personnel involved in the care of patients and the support of response activities.

Institute of Medicine Report

Calling the Shots: Immunization Finance Policies and Practices

In 2000, the IOM released its report, *Calling the Shots: Immunization Finance Policies and Practices*, which examined the roles and responsibilities of state and federal governments in supporting immunization programs and services. The IOM formed the Committee on Immunization Finance Policies and Practices to look particularly at one of the programs administered by the CDC— the Section 317 program, that makes annual awards to states to help them purchase vaccines and support immunization programs. The IOM report recommended additional federal and state funding to purchase vaccines for the nation's poorest individuals and greater financial and administrative support for state and local immunization programs. The IOM also recommended that federal and state agencies develop a set of consistent immunization monitoring measures. Four regional meetings were held to promote the study's conclusions and recommendations. In 2001, meetings were held in Chicago and Austin, Texas, and in 2002, regional meetings took place in Los Angeles and Washington, D.C.

In 2002, the IOM is conducting a follow-up designed to help identify the most effective ways to finance the purchase and delivery of vaccines. The new study, *Purchasing recommended vaccines: Financing options for public and private sector in the United States* will address five questions:

1. What are the roles and responsibilities of public and private agencies and health care providers in financing the purchase and administrative costs of vaccines to achieve national immunization objectives for all children, adolescents and adults in the U.S.?
2. In working towards an appropriate balance of roles and responsibilities, what finance strategies best achieve national goals and best fit the service delivery mechanisms for various vaccines and/or population groups?
3. What are the current levels of need for recommended vaccines in the child, adolescent, and adult populations for those persons who do not have health plan benefits that include immunizations or who have large co-payments and/or deductibles?
4. What methods could reduce the time lag and disparities that occur between new vaccine recommendations and the availability of public and private financing to implement the recommendation?
5. Will vaccine products under consideration for licensing have a significant effect on future vaccine purchase strategies in public and private health plans?

Government Performance and Results Act

Government agencies are required by the Government Performance and Results Act to establish goals to improve the immunization coverage level of two-year-old children enrolled in Medicaid. The agencies are also required to outline processes to measure those goals. As part of this project, NIP presents workshops to promote collaboration between state immunization programs and state Medicaid agencies. In 2001, all states and the District of Columbia were participating in this immunization program.

Meeting Challenges

Response to Bioterrorism: Smallpox Preparedness

In light of the events of September 11, 2001, the NIP joined with a number of CDC programs, the Department of Health and Human Services, and other federal and state agencies to strengthen efforts related to smallpox bioterrorism preparedness. The threat of the reintroduction of smallpox into the world is heavy. Because of the possibility that the smallpox virus could be used as a bioterrorism agent with the potential for its spread in a largely unvaccinated population, CDC issued an updated *Interim Smallpox Response Plan and Guidelines*. This document will help federal, state, and community partners mobilize, coordinate, communicate, and expand resources targeted toward smallpox preparedness.

The following smallpox response actions are under way:

Interim Smallpox Response Plan and Guidelines

The *Interim Smallpox Response Plan and Guidelines* was broadly distributed to federal, state, and local partners to assist them in their smallpox preparedness efforts. This plan is a "living" document that will be continually revised and updated to address new and emerging issues and developments.

Smallpox Vaccine Stockpile

Two contracts have been signed for the production of 155 million doses of smallpox vaccine by the end of 2002. These vaccines will be added to existing smallpox vaccine supply for a total of 286 million doses. At that point, there will be enough smallpox vaccine in the nation's vaccine stockpile to protect every citizen in the U.S., if needed.

CDC Smallpox Response Teams

In the event of a smallpox outbreak, CDC will send CDC Smallpox Emergency Response teams to the emergency site. Each team includes physician team leaders, senior public health advisors, medical epidemiologists, laboratory scientists, communications specialists, community liaison specialists, and computer and information technology specialists.

Smallpox Training Programs and Courses

The National Immunization Program partnered with the CDC's National Center for Infectious Diseases to develop curricula, training manuals and materials, and speakers for smallpox training. These training programs and courses were offered to CDC Smallpox Emergency Response team members, other federal agencies, and state and local health officials. By March 2002, NIP will have provided smallpox training for over 300 CDC employees, 200 state and local public health officials, and 30 of NIP's partners. In addition, the smallpox satellite broadcast course for health care providers was seen by approximately 140,000 health care professionals.

Smallpox Materials Development

Tools and systems are under development for rapidly communicating smallpox information and updates to health care providers, state and local immunization programs, community leaders, the general public, and the media. This includes smallpox education materials and other information to be placed on CDC websites.

Providing Guidance for Managing Vaccine Delays and Shortages

The supply of a number of universally-recommended vaccines became fragile in 2001. Health care providers reported delays and shortages for the following vaccines: DTaP, MMR, Tetanus-diphtheria (Td), varicella, influenza, and pneumococcal conjugate vaccines.

A variety of factors have lead to the present vaccine supply delay and shortages. Some of the shortages, for example have been caused by companies leaving the market. In other cases, manufacturing or production problems caused delays in shipments and distribution of vaccines. Some manufacturers have experienced, decreased yields, a result of moving to different vaccine formulations.

To address the vaccine delays and shortages, CDC and other federal agencies have taken a number of actions:

Working with the ACIP to Provide Priority by Risk Groups and Age in Immunization Recommendations and Schedules

Health care providers who experience temporary shortages are recommended to give the vaccines they have to those patients who need them most. For example, the first vaccines available should be given to infants needing the recommended childhood vaccinations and to people in high risk groups. In addition, the ACIP recommended temporary suspension of routine Td boosters for adolescents and adults.

Coordinating Vaccine Amounts Provided to the 64 Immunization Project Grantees

The National Immunization Program coordinates with the vaccine manufacturers to help ensure equitable distribution of the vaccine to the 64 grantees. Manufacturers notify NIP of the amount of vaccine available for the grantees from each lot release. Based on the information from the central vaccine depots, NIP then informs the manufacturers which grantees should receive the first shipments and how much each grantee should receive.